

REMARKS

1. In response to the Office Action mailed January 7, 2009, Applicants respectfully request reconsideration. Claims 1-6, 8-17, 20-21, 24-26, and 28-62 were last presented for examination. In the outstanding Office Action, claims 1-6, 8-17, 20, 21, 24-26 and 28-62 were rejected. By the foregoing Amendments, no claims have been amended, added or cancelled. Upon entry of this paper, claims 1-6, 8-17, 20, 21, 24-26 and 28-62 will be pending in this application. Of these fifty-six (56) claims, four (4) claims (claims 1, 24, 29 and 59) are independent.

2. Based upon the above Amendment and following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Art of Record

3. Applicants acknowledge receipt of form PTO-892 listing additional references identified by the Examiner.

Claim Rejections under §103

4. Claims 1-3, 8, 14-17, 20, 24, 28-30, 32-35, 39, and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,119,044 to Kuzma (hereinafter, "Kuzma") in view of U.S. Patent No. 5,123,422 to Charvin (hereinafter, "Charvin"). Applicants respectfully request that the Examiner reconsider and withdraw these rejections for at least the following reasons.

The Combination of Kuzma and Charvin is prima facie Improper

5. The proposed combination of Kuzma and Charvin is *prima facie* improper because the Examiner has failed to provide an appropriate basis for making the proposed combination. As stated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently known in the prior art." (127 S.Ct. 1727, 1741 (2007).) The Supreme Court

recognized that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some *articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*” (See KSR, 127 S.Ct. at 1741 (citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006); emphasis added.) Applicants submit that the Examiner has completely failed to satisfy these legal obligations. The Examiner has done what has been viewed as circumspect by the Supreme Court and has only provided a conclusory and unsupported statement to justify the proposed combination of Kuzma and Charvin.

6. Kuzma is directed to an implantable electrode array adapted to be inserted into the cochlea, and which assumes a shape to hug the modiolar wall of the cochlea after insertion. A naturally curved positioning stylet made of shape-memory metal is cooled into a straight shape and inserted into the electrode array. As the stylet warms to body temperature, it returns to its spiral memory shape, causing the electrode array to also assume a spiral shape, thus positioning the electrode contacts against the modiolar wall. (See, Kuzma, Abstract.) FIG. 4 of Kuzma shows an electrode array which was formerly straight (shown as broken lines) but is now in a curved configuration. Kuzma further states that “soft tip 37, having a depth of distance L8, is typically formed from LSR-25 at the very distal tip of the electrode array 30. In the preferred embodiment, L8 has a value of approximately 0.3 mm.” (See, Kuzma, col. 11, ll. 39-42.)

7. Charvin is directed to a system which is said to solve the problem of “producing electrode carriers which retain their orientation when inserted into the cochlea so that the stimulation electrodes 11 all remain placed on the inside over the whole length of the electrode carrier.” (See, Charvin, col. 8, ll. 41-45.) As Charvin explains, when a rod having a “conform and continuous circular section” is “inserted into a spiral circuit, the internal fibers are compressed and the external fibers are tensioned and these internal stresses result in the rod twisting around its axis.” (See, Charvin, col. 8, ll. 47-50.) Charvin continues, “the problem raised is solved... by electrode carriers in which the distal part 22... is constituted by section 15 interconnected by hinges 16 around each of which two successive sections can pivot with respect to each other.” (See, Charvin, col. 8, ll. 51-56.)

8. Charvin states that “an electrode carrier cut into joined successive sections has the *advantage of...* [being] easily inserted inside the cochlea and, at the same time, of *bending easily* in order to take up the helical shape of the cochlea.” (See, Charvin, col. 8, ll. 57-62.) As shown in FIGS. 2-5 of Charvin, the “distal part comprises transversal slits 12” over the distal part of the carrier. Charvin further states that “body 6 is divided into successive sections by *slits 12...* and *which cut at least across half the width of body 6 and preferably up to three-quarters*, since the object is to constitute veritable hinges around an axis of given direction and *not just to give flexibility* in any direction as in other heretofore known designs.” (See, Charvin, col. 9, ll. 13-21.) Furthermore, Charvin states, “*slits 12 facilitate bending and ensure that the bending and/or compression stresses are not created in the external and/or internal fiber.*” (See, Charvin, col. 9, ll. 39-41.)

9. In the Office Action, the Examiner states that Kuzma teaches substantially Applicants’ invention as claimed, but admits that Kuzma “fails to teach a conical tapered portion tapering and extending distally from the distal end of the electrode array.” (See, Office Action, pg. 4, ¶ 15.) The Examiner then asserts that “Charvin teaches that it is known to have a conical tapering at the distal end of an electrode array... for providing the predictable results of preventing fold-over of the tip member, facilitating insertion of the electrode array, and conforming to the natural geometry and shape of the cochlea.” (See, Office Action, pg. 5, ¶ 15.) The Examiner relies on Charvin as teaching a conical tapering distal end of an electrode array, asserting that it would have been obvious to modify the Kuzma device to have a conical tapered portion at the distal end. The Examiner attempts to support this assertion by further asserting that “such a modification was known in the art to provide the predictable results of *preventing fold-over* of the tip member, facilitating insertion of the electrode array and providing a *more rigid support* to facilitate placement, and providing for the electrode array to conform to the natural shape and geometry of the cochlea.” (See, Office Action, pg. 5, ¶ 15.) However, the Examiner provides nothing more than this conclusory statement as support.

10. Applicants assert that, in fact, one having ordinary skill in the art would not have been motivated to modify Kuzma in view of Charvin, as suggested by the Examiner. As explained above, Kuzma required that its electrode array as well as its tip be flexible such that it could

follow the modiolar wall when implanted but not so flexible so as to allow foldover during insertion of the array into the cochlea. However, contrary to the Examiner's statement justifying the suggested combination, Charvin would not in fact "prevent fold-over" and provide a "more rigid support to facilitate placement", since a plurality of "slit" or "hinges" provided along the carrier would more likely aid fold-over of the distal end of a carrier member. Particularly given that the "slit" is cut through the carrier member at least one-half across its body, and more preference three-quarters across the body, the distal end is actually made more flexible, and not less flexible (preventing fold-over) as claimed by the Examiner. Therefore, one of ordinary skill in the art would not have been motivated to modify Kuzma with the teachings of Charvin, since an electrode array provided with slits cut half-way or three-quarter into the carrier body would not inform a person having ordinary skill to modify the flexible electrode array of Kuzma so as to "prevent foldover", or to provide a "more rigid support to facilitate placement", when *Charvin actually makes the carrier member more flexible*, not less, and *"ensure[s] bending and/or compression stresses are not created in the external and/or internal fiber,"* thus doing the opposite of "preventing foldover," as noted above. Because, as explained above, the Examiner has completely failed to provide any rational underpinning to justify the proposed combination, Applicants assert that the proposed combination of Kuzma with Charvin is *prima facie* improper and that the rejections under 35 U.S.C. §103 should be reconsidered and withdrawn.

***The Proposed Combination of Kuzma and Charvin
is based on Impermissible Hindsight***

11. Applicants further assert that the combination of Kuzma and Charvin is *prima facie* improper because the reasoning provided by the Examiner to combine the cited references is based on impermissible hindsight. As stated in Section 2142 of the Manual of Patent Examining Procedure (M.P.E.P.), the "[E]xaminer must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made." The Examiner must then examine the claimed invention and determine whether the invention as a whole would have been obvious to that hypothetical person. (See, M.P.E.P., §2142.) Although this is inherently an analysis based on hindsight,

“impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” (See, M.P.E.P., §2142.) The Examiner must consider only the prior art, and knowledge derived from Applicants’ disclosure must be put aside in reaching this determination. (See, *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).)

12. As described above, Kuzma is directed to an implantable electrode array adapted to be inserted into the cochlea, and which assumes a shape to hug the modiolar wall of the cochlea after insertion. (See, Kuzma, Abstract.) There is absolutely no teaching or suggestion in Kuzma, or the other art of record, that would lead one of ordinary skill in the art to incorporate an inflexible metal tip, whether shaped to be conically tapering, where the body of the electrode array is encased in an inflexible metal sheath. Such incorporation of an inflexible metal tip which is said to be used in conjunction with an inflexible metal sheath body would fundamentally frustrate or prevent the usage of the flexible electrode array of Kuzma in a way that would destroy the purpose for which Kuzma is intended. Therefore, Applicants assert that the Examiner has based the proposed combination of impermissible hindsight drawn directly from Applicants’ disclosure, piecing together features of various references in an attempt to produce Applicants’ claimed invention. Accordingly, Applicants assert that the combination of Kuzma and Charvin is *prima facie* improper, and that the rejections under 35 U.S.C. §103 should be withdrawn.

***The Proposed Combination Still Fails to Contain
All Elements of Applicants’ Claimed Invention***

13. As set forth in §2142 of the M.P.E.P., “to establish a *prima facie* case of obviousness... the prior art reference (or references when combined) must teach or suggest all of the claim limitations.” Applicants respectfully assert that even if the references were combined as proposed by the Examiner, the resulting combination would still fail to teach all elements of Applicants’ claimed invention.

14. As explained in detail above, Charvin is directed to a carrier member in which slits or hinges half-way or preferably three-quarters across the carrier member’s body, making it more flexible so as to prevent bending stresses. The slits and hinges both act to make the carrier member *more flexible*, and not less flexible so as to “prevent foldover.”

15. In contrast, Applicants' independent claim 1 recites, in part, "a tip member comprising a *conical tapered portion*... wherein said tip member is configured such that *the dimensions and shape of said flexible conical tapered portion of said tip member prevents substantial foldover of said tip* when a deflection/impact force is applied to said tip member during implantation into the cochlea." (See, Applicants' claims 1 and 24, as amended above; emphasis added.) Applicants assert that even if the carrier member having slits cut half-way or three-quarters of their way into the body were to be combined with the Kuzma device for the reason given by the Examiner, the combination would result in a device which fails to teach or suggest all claim limitations of Applicants' claimed invention.

16. Furthermore, Applicants' independent claims 29 and 59 recite, in part, "such that *the dimensions and shape of said conical tapered portion of said tip member causes at least a portion of said tip member to operate* as a constant-strength *cantilever beam* when the deflection/impact forces are applied to said tip member during implantation." (See, Applicants' independent claim 29, as amended above; emphasis added.) Similarly, independent claim 59 recites, in part, "such that *the dimensions and shape of said conical tapered portion of said tip member prevents substantial foldover* of said tip member when a deflection/impact force is applied to said tip member during implantation." (See, Applicants' independent claim 59, as amended above; emphasis added.) Clearly, with both independent claims 29 and 59, Applicants' tip is dimensioned and shaped so as to prevent foldover during implantation. To the contrary, the highly flexible carrier member of Charvin, even if properly combined with the flexible electrode array of Kuzma, is configured to easily bend or flex, rather than "preventing foldover."

17. Therefore, for at least the reasons presented above, and based on Applicants' presently presented Amendments, Applications assert that neither Charvin nor Kuzma, alone or in combination with each other or any other art of record, teach all elements of Applicants' claims 1, 24, 29 and 59, and therefore the rejections under Section 103 of these claims are improper. Accordingly, Applicants respectfully request that these rejections be reconsidered and that they be withdrawn.

Dependent claims

18. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

Conclusion

19. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

20. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicants reserve the right to pursue such claims in a continuation or divisional application.

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